Exhaled Nitric Oxide and Exhaled Breath Condensate Measurement for Respiratory Disorders

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<thead>
<tr>
<th>Type:</th>
<th>Policy Specific Section:</th>
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<tbody>
<tr>
<td>Investigational / Experimental</td>
<td>Medicine</td>
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<tr>
<th>Original Policy Date:</th>
<th>Effective Date:</th>
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<tr>
<td>March 1, 2006</td>
<td>September 27, 2013</td>
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Definitions of Decision Determinations

**Medically Necessary:** A treatment, procedure or drug is medically necessary only when it has been established as safe and effective for the particular symptoms or diagnosis, is not investigational or experimental, is not being provided primarily for the convenience of the patient or the provider, and is provided at the most appropriate level to treat the condition.

**Investigational/Experimental:** A treatment, procedure or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

**Split Evaluation:** Blue Shield of California / Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a Split Evaluation, where a treatment, procedure or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

Description

Nitric Oxide (NO) is produced by the human lung and is present in the exhaled breath. It has been implicated in the pathophysiology of lung diseases, including asthma. Current techniques for diagnosing and monitoring asthma and predicting exacerbations are suboptimal. Two new
strategies, evaluation of exhaled nitric oxide and exhaled breath condensate are proposed. These techniques are also potentially useful in the management of other conditions such as chronic obstructive pulmonary disease (COPD) and chronic cough. However, there is insufficient evidence through lack of studies to determine the effect of exhaled nitric oxide and exhaled breath condensate tests on health outcomes, and require further evaluation. These tests are therefore considered investigational.

**Policy**

The following tests are considered investigational in the diagnosis and management of asthma and other respiratory disorders including, but not limited to, chronic obstructive pulmonary disease and chronic cough:
- Measurement of exhaled nitric oxide
- Measurement of exhaled breath condensate

**Policy Guideline**

There is a CPT code specific to direct determination of exhaled nitric oxide (e.g., using the NIOX system):
- 95012: Nitric oxide expired gas determination
- 83987: pH; exhaled breath condensate

A variety of substances has been analyzed in a collected sample of exhaled breath condensate, including but not limited to leukotrienes, cytokines, and other substances reflecting oxidative stress. The above CPT code would not apply to this expanded analysis of exhaled breath condensate. It is likely that specific CPT codes describing the underlying laboratory technique for analysis would be used.

**Documentation Required for Clinical Review**

- No records required

The materials provided to you are guidelines used by this plan to authorize, modify, or deny care for persons with similar illness or conditions. Specific care and treatment may vary depending on individual need and the benefits covered under your contract. These Policies are subject to change as new information becomes available.